IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PAUL BENTZLEY	:	CIVIL ACTION
	:	NO. 10-3827
Plaintiff,	:	
	:	
v.	:	
	:	
MEDTRONIC, INC., et al.,	:	
	:	
Defendants.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. NOVEMBER 28, 2011

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Before the Court is Defendants' Motion for Summary Judgment on Plaintiff's products liability, negligence, and breach of warranty claims under Pennsylvania law. The issue before the Court is whether the Medical Device Amendments of 1976 ("MDA") expressly preempt certain state law claims. For the reasons that follow, the Court will grant Defendants' motion on all of Plaintiff's claims except for the claim for breach of express warranty.

I. BACKGROUND

A. Premarket Approval of Model MMT-522 Paradigm Real-Time Insulin & Glucose Monitoring System

Medtronic, Inc., and Medtronic Minimed, Inc. ("Defendants") manufacture and distribute the Model MMT-522 Paradigm Real-Time Insulin & Glucose Monitoring System ("MMT-522 System").[1] That system provides continuous glucose monitoring and consists of three components: a real-time continuous glucose sensor, a radio frequency transmitter, and a "smart" insulin pump. Am. Compl. ¶¶ 14-15. The system delivers insulin "automatically and continuously 24-hours a day." Paradigm 522 and 722 Insulin Pumps User Guide 1, ECF No. 36-5 (hereinafter

[1] Medtronic, Inc., is a corporation organized under Minnesota law with its principal place of business in Minnesota. Am. Compl ¶ 7; Answer ¶ 7. Medtronic Minimed, Inc., is a corporation organized under Delaware law with its principal place of business in California. Am. Compl. ¶ 8; Answer ¶ 8.

"User Guide"). The MMT-522 System is a Class III medical device approved by the U.S. Food and Drug Administration ("FDA"). Faillace Decl. ¶ 5, ECF No. 36-3.

Medical devices intended for human use fall into three classes based on their risk to consumers. See 21 U.S.C. § 360c(a)(1);[2] Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Class I devices are subject only to "general controls," which involve the lowest level of oversight. § 360c(a)(1)(A); Riegel, 552 U.S. at 316. Class II devices are subject to "special controls," such as performance standards and post-market surveillance measures. § 360c(a)(1)(B); Riegel, 552 U.S. at 317. And Class III devices are subject to the highest level of federal oversight. § 360c(a)(1)(C). "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" Riegel, 552 U.S. at

[2] Unqualified § 360 et seq. numbers hereinafter refer to sections of Title 21 of the U.S. Code.

317 (quoting § 360c(a)(1)(C)(ii)). A new Class III device must receive premarket approval from the FDA.[3] Id.

Upon receiving premarket approval, a manufacturer may not change any aspect of the device that would affect its safety or effectiveness without first receiving FDA approval by "supplemental application." § 360e(d)(6)(A)(i). A supplemental application is "evaluated under largely the same criteria as an initial application." Riegel, 552 U.S. at 319 (citing § 360e(d)(6); 21 C.F.R. § 814.39(c)).

Defendants received premarket approval pursuant to a supplemental application for the MMT-522 System. On June 15, 1999, the FDA approved Defendants' premarket application for the Minimed Continuous Glucose Monitoring System. Faillace Decl. ¶ 6.[4] The FDA advised Defendants that the appropriate pathway to market approval for the MMT-522, the modified system, would be

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[3] MDA grandfathered devices sold before its effective date until the FDA required further procedural review of those grandfathered devices. Riegel, 552 U.S. at 317. To limit the competitive advantage grandfathered devices would gain, MDA exempts from premarket approval devices that are "substantially equivalent" to another device of its type. § 360c(f)(1)(A). The FDA's review for substantial equivalence is termed the § 510(k) notification process, which refers to the statutory provision describing the substantial review process. Most new Class III devices receive market approval under the § 510(k) process. See Riegel, 552 U.S. at 317 (reviewing MDA grandfather provision and § 510(k) process).

[4] The original premarket approval letter is publicly available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=p980022.

by supplemental application for premarket approval, not the § 510(k) notification process.[5] Id. ¶ 7. Defendants filed the supplemental application and, on April 7, 2006, after a six-month review process, the FDA approved the requested modifications to the original device "to enable the pump to accept data from the sensor, and to enable the sensor to communicate directly to the pump." Id. Ex. A.

B. Plaintiff's MMT-522 System

Paul Bentzley ("Plaintiff") suffers from Type One diabetes, which requires him to infuse insulin into his body to control his blood-sugar levels.[6] Barilla Dep. 8:20-25, Mar. 1, 2011, ECF No. 36-4. Plaintiff's physician, Dr. Donald Barilla, prescribed the MiniMed 507c insulin pump in 1998. Letter from Dr. Barilla 2 (Oct. 13, 1998), ECF No. 36-4. In 2003, Dr. Barilla prescribed the MMT-512 pump, the predecessor to the MMT-522. Letter from Dr. Barilla 1 (June 17, 2003), ECF No. 36-4. Those two devices are not at issue in this case.

On April 8, 2008, a sales representative for Defendants called Plaintiff regarding replacement of his MMT-512 Pump. Notification Activities/Tasks Log for Paul Bentzley 1, ECF

[5] The MMT-522 pump is based on the Class II MMT-515 pump.

[6] Plaintiff is a resident of Pennsylvania. Am. Compl. ¶ 6.

No. 36-6 (hereinafter "Tasks Log"); Defs.' Resp. to Pl.'s Interrog. No. 2, at 3, ECF No. 36-6. On April 8, 2008, the representative faxed to Dr. Barilla's office a sample prescription and statement of medical necessity for an MMT-522 Pump. Defs.' Resp. to Pl.'s Interrog. No. 2, at 3; Facsimile from Medtronic MiniMed (April 8, 2008), ECF No. 36-4. On April 14, 2008, a representative of Dr. Barilla's office advised Defendants that Dr. Barilla had not seen Plaintiff since 2004 and would need to conduct laboratory tests before prescribing a replacement pump. Defs.' Resp. to Pl.'s Interrog. No. 2, at 3; Tasks Log 2.

On May 8, 2008, Plaintiff was seen by Dr. Barilla. Defs.' Resp. to Pl.'s Interrog. No. 2, at 3; Facsimile from Medtronic MiniMed (April 8, 2008) (reflecting notations "update pt seen on 5/8/08" and "updated had 5-8-08 appt"). On May 14, 2008, Dr. Barilla's office faxed to Defendants a signed prescription and letter of medical necessity for Plaintiff's use of the MMT-522 pump. Defs.' Resp. to Pl.'s Interrog. No. 2, at 3-4; Barilla Dep. 59:7-61:2 & Ex. 6. On May 19, 2008, Defendants shipped the pump used with the MMT-522 System to Plaintiff. Invoice No. 94841304 (May 19, 2008), ECF No. 36-3; Defs.' Resp. to Pl.'s Interrog. No. 2, at 4. And, after receiving a narrative prescription letter signed by Dr. Barilla on May 21, 2008, for the set of transmitters and sensors that complement the MMT-522

pump to form the MMT-522 System, Defendants shipped the transmitters and sensors to Plaintiff on the same day. Invoice No. 94853287 (May 22, 2008), ECF No. 36-3, Ex. 4-B; Defs.' Resp. to Pl.'s Interrog. No. 2, at 4.

On October 28, 2008, Plaintiff failed to receive the correct dosage of insulin to manage his diabetic condition from the MMT-522 System. Am. Compl ¶ 20. As a result, he was hospitalized for diabetic ketoacidosis and required medical procedures and further hospitalization. Id. Plaintiff alleges that his MMT-522 System malfunctioned from exposure to high-strength electromagnetic fields to which he was exposed during his employment. Id. ¶ 21. Plaintiff claims that he was not warned that his MMT-522 System could malfunction from such exposure, despite a Class 2 Recall regarding this warning in 2007.[7]

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[7] From April 27, 2007, to May, 4, 2007, Defendants mailed a Medical Device Safety letter to healthcare professionals and existing users of certain insulin pump models that reiterated existing warnings to avoid exposing the pumps to high-strength electromagnetic fields. Cragle Decl. ¶¶ 5-10, ECF No. 36-3; Tupper Decl. ¶ 6. The FDA classified the mailing as a "Class 2 Recall" for certain insulin pumps and noted that Defendants are "also including an insert with this information with any Paradigm infusion pumps shipped to new customers." See Medical & Radiation Emitting Device Recalls, U.S. Food and Drug Admin. (July 7, 2007), http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=52313.

Plaintiff had not yet even owned the MMT-522 System during the 2007 recall. That Defendants mailed additional warnings regarding the risk of damage from electromagnetic

C. Procedural History

On August 2, 2010, Plaintiff commenced this action against Defendants. Compl., ECF No. 1. On October 27, 2010, Plaintiff filed an Amended Complaint (ECF No. 12) that asserts claims for strict liability (Count I), marketing defect (failure to warn) (Count II), design defect (Count III), manufacturing defect (Count IV), breach of express warranty (Count V), breach of implied warranty of fitness for a particular purpose (Count VI), breach of implied warranty of merchantability (Count VII), negligence (Count VIII), and punitive damages (Count IX).[8]

Defendants filed a motion to dismiss Plaintiff's Amended Complaint. Specifically, Defendants argued that Counts I, II, III, IV, VI, and VII failed to state claims under Pennsylvania law. Mot. to Dismiss, ECF No. 13. Defendants did not argue, as they do here, that Plaintiff's claims are preempted by federal law. Following a hearing, the Court denied Defendants' Motion to Dismiss and the parties proceeded with discovery. Order, Jan. 19, 2011, ECF No. 22.

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fields during the 2007 recall period is immaterial. However, whether Plaintiff received the warning for the MMT-522 System in 2008 is an issue that will be considered below.

[8] Plaintiff's "Count IX" for punitive damages will be construed as a demand for relief based on Counts I through XIII because there is no independent cause of action for "punitive damages."

On April 20, 2011, Defendants filed their Motion for Summary Judgment, which is now before the Court. Plaintiff filed a Response in Opposition on May 9, 2011. ECF No. 38. Defendants replied on June 6, 2011. ECF No. 40. On June 10, 2011, Plaintiff moved for leave to file a surreply. ECF No. 41. On October 10, 2011, Defendants moved for leave to file a supplemental memorandum with respect to a recent FDA ruling that related to the case. ECF No. 43. On October 18, 2011, Plaintiff answered Defendants' motion. ECF No. 44. And, on November 1, 2011, Defendants filed a reply in further support of their supplemental memorandum. ECF No. 45. The Court considered all of the above pleadings and the matter is now ripe for review.[9]

II. DISCUSSION

Defendants argue that MDA preempts all of Plaintiff's claims because the MMT-522 System received premarket approval, or, in the alternative, that Counts I, VI, and VII of the Amended Complaint are barred by Pennsylvania law. Mot. for Summ. J. 1. Plaintiff, on the other hand, argues that its claims are not preempted nor barred by Pennsylvania law.

[9] The Court has diversity jurisdiction. See 28 U.S.C. § 1332(a).

A. Standard of Review

Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A motion for summary judgment will not be defeated by 'the mere existence' of some disputed facts, but will be denied when there is a genuine issue of material fact." Am. Eagle Outfitters v. Lyle & Scott Ltd., 584 F.3d 575, 581 (3d Cir. 2009) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986)). A fact is "material" if proof of its existence or nonexistence might affect the outcome of the litigation, and a dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248.

The Court will view the facts in the light most favorable to the nonmoving party. "After making all reasonable inferences in the nonmoving party's favor, there is a genuine issue of material fact if a reasonable jury could find for the nonmoving party." Pignataro v. Port Auth. of N.Y. & N.J., 593 F.3d 265, 268 (3d Cir. 2010). While the moving party bears the initial burden of showing the absence of a genuine issue of material fact, meeting this obligation shifts the burden to the nonmoving party who must "set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 250.

B. Preemption

The Supremacy Clause provides that the laws of the United States "shall be the supreme Law of the Land." U.S. Const. art VI, cl. 2. Out of this command, Congress may preempt state action in three ways: "State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment." Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001) (internal quotation marks and citations removed). Here, the Court is concerned only with express preemption.

MDA expressly preempts certain state law medical device requirements that are different from, or in addition to, applicable federal law.[10] In determining whether MDA preempts

[10] MDA provides, in relevant part:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement——
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Plaintiff's state law claims, the Court must first determine "whether the Federal Government has established requirements applicable [to the device at issue]." See Riegel, 552 U.S. at 321. If there are applicable federal requirements, then the Court must next determine whether Plaintiff's "common-law claims are based upon [Pennsylvania] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." See id. at 321-22 (quoting § 360k(a)). The parties do not take issue with whether Plaintiff's claims are based on Pennsylvania requirements that relate to the safety and effectiveness of the MMT-522 System. However, Plaintiff argues that its claims are not preempted because the pump used with the MMT-522 System underwent § 510(k) notification review and that its state law claims are parallel to the applicable federal requirements.

1. The Federal Government Established Requirements Applicable to the MMT-522 System

The FDA promulgated a regulation that provides that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a

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§ 360k(a) (2006). Subsection (b) permits the FDA to exempt state requirements in certain circumstances.

particular device . . . .” 21 C.F.R. § 808.1(d). The “substantial equivalence” clearance under the § 510(k) notification process “does not impose any federal ‘requirement’ applicable to the device, but is rather a ‘generic federal standard.’” Horn v. Thoratec Corp., 376 F.3d 163, 168 (3d Cir. 2004) (quoting Lohr, 518 U.S. at 486-87 (plurality)). However, premarket approval under the more rigorous § 360e(c) process imposes “requirements” under MDA. Riegel, 552 U.S. at 322; Horn, 376 F.3d at 173 (holding that premarket approval of heart pump imposed “specific federal requirements” that preempt state law claims of manufacturing and design defect and defect based on failure to warn).

Defendants produced evidence that the device at issue is the MMT-522 System, which incorporates the pump used with the MMT-522 System and received the more-rigorous premarket approval from the FDA. Defendants have provided evidence in the form of the FDA’s approval letter, which confirms that the MMT-522 System, including the pump used in that system, received premarket approval.

And the FDA has recently confirmed that the MMT-522 System, including the pump used in that system, received premarket approval. On September 23, 2011, the FDA rejected a Citizen Petition that requested clarification of the April 7, 2006, letter granting premarket approval of the MMT-522 System.

Citizen Pet. (Nov. 9, 2010), ECF No. 43-1. Specifically, Petitioner sought to amend the letter by adding the following language:

> This approval is limited solely to the ability of the pump to accept data from the sensor and the ability for the sensor to communicate directly to the pump, and this approval does not extend to the pump itself.

Citizen Pet. 2. On September 23, 2011, the FDA responded by letter and rejected the Petition. The FDA first noted that "[t]he Paradigm System consists of the Paradigm MMT-522/722 external insulin infusion pump ('the 522 Pump') and a continuous glucose monitor, the Guardian RT sensor." Letter from FDA (Sept. 23, 2011), ECF No. 43-1. Furthermore, the FDA observed that "Medtronic modified the 515 Pump and the Guardian RT sensor and combined them to create the Paradigm System." Id. at 2. As required by the FDA, Medtronic "submitted a PMA supplement for the Paradigm System (P980022/S013) on October 3, 2005." Id. "Accordingly, FDA approved the PMA supplement for the Paradigm System, including both the 522 pump and the Guardian RT sensor, on April 7, 2006. . . . Because the approval letter, as issued, applies to the Paradigm System as a whole, we deny your [Petitioner's] request to amend the approval letter by adding the [suggested] language . . . ." Id.

Plaintiff attempts to raise an issue of material fact by arguing that the MMT-522 pump is "separate and apart from the

insulin infusion system and did not gain approval through the PMA process." Pl.'s Surreply 2. Plaintiff points out that the Class 2 recall was for pumps, not the monitoring system and that the pump was shipped separately from the transmitters and sensors, which completed the MMT-522 System. Id. But Plaintiff's arguments are not in accord with the facts before the Court nor do they have legal support.

First, Plaintiff has not produced evidence of record that the pump component of the MMT-522 System received approval under the § 510(k) process or that the pump did not receive premarket approval. Plaintiff argues that a May 21, 2004, letter from the FDA approving MMT-515/715 pumps under the § 510(k) process indicates that the pump used in the MMT-522 System received § 510(k) approval. Pl.'s Answer to Defs.' Mot. for Summ. J. 7. Plaintiff refers to a letter from Defendants' counsel that he claims "reiterat[es] that the FDA's April 7, 2006, letter giving 510(k) clearance to the MMT-515 also approved the MMT-522 pump." Id. In fact, on its face, it is clear that Defendants' counsel's reference to the FDA's April 7, 2006, letter actually refers to the FDA's premarket approval of a supplement application for the MMT-522. See Id. Ex. D, at 2. And even if Plaintiff proffered evidence that the pump received § 510(k) approval, Plaintiff failed to raise a genuine issue of

material fact whether the MMT-522 System, including the pump, received premarket approval.

Furthermore, Plaintiff's reliance on the Class 2 recall is misplaced here. Indeed, the 2007 recall did not involve the system by which Plaintiff was allegedly injured and ended before Plaintiff even received the MMT-522 System. The recall only required Defendants to mail additional warnings regarding exposure to electromagnetic fields;[11] it did not require Defendants to replace any products. The recall has no bearing on whether the MMT-522 System received premarket approval, much less that there were federal "requirements" relating to the MMT-522 System.

Second, Plaintiff's contention that, in considering a preemption issue, the Court must break a medical device into its component parts, is without legal support. In fact, courts that have dealt with this issue have done just the opposite. See Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 657 (S.D. Tex. 2010) (finding hip-replacement system received premarket approval even though component initially approved via § 510(k) process); Cornwell v. Stryker Corp., No. 10-066, 2010 WL 4641112, at *3 (D. Idaho Nov. 1, 2010) (same); Bass v. Stryker

[11] Plaintiff's argument regarding Defendants' compliance with the recall may be relevant, however, in considering whether Plaintiff's claims parallel the relevant federal requirements.

Corp., No. 09-632, 2010 WL 3431637, at *4 (N.D. Tex. Aug. 31, 2010) (same).

Therefore, based on the evidence of record, the device at issue in this case is the MMT-522 System. Plaintiff has failed to proffer evidence to the contrary. Because the FDA granted premarket approval for the MMT-522 System, the Court finds that the Federal Government has established requirements applicable to the relevant device. See Riegel, 552 U.S. at 322.

2. Whether Plaintiff's Claims are Based on Parallel Federal Requirements

Plaintiff's claims are preempted under MDA "only to the extent that they are 'different from, or in addition to,' the requirements imposed by federal law." See Riegel, 552 U.S. at 330 (citing § 360k(a)(1)). "Generalized common law theories of liability . . . are precisely the types of claims the MDA sought to preempt." Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010) (citing Riegel, 552 U.S. at 325).

However, parallel state duties——duties that are not different from, or in addition to, federal requirements——are not preempted by MDA. Medtronic, Inc. v. Lohr, 518 U.S. 470, 494-95 (1996). And a state may provide a damages remedy for violations of common-law duties that parallel federal requirements. Riegel, 552 U.S. at 330 (noting that "§ 360k does not prevent a State

from providing a damages remedy for claims premised on a violation of FDA regulations" but preserving the issue for the district court in the first instance); Lohr, 518 U.S. at 495.

In Lohr, Medtronic received market approval under § 510(k)'s expedited notification process for its Model 4011 pacemaker lead, which was found to be "substantially equivalent" to devices already on the market. The pacemaker lead is the portion of a pacemaker that transmits an electrical signal to the heart. The Model 4011 pacemaker lead did not receive the more rigorous premarket approval. Lohr was implanted with a Medtronic pacemaker equipped with the Model 4011 lead, which later failed because, according to Lohr's physician, a defect in the lead. Lohr and her husband brought claims in negligence and strict liability under Florida law. In part, the Lohrs theory of recovery was based on Medtronic's alleged violations of FDA "good manufacturing practices" regulations, which establish requirements for a device's manufacture, and labeling requirements. See 21 C.F.R. §§ 820.1-820.250.

MDA did not preempt the Lohrs' allegations because they "may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. Lohr, 518 U.S. at 495. Even if Florida law required the Lohrs to prove violations of federal regulations by negligent conduct or that the violations created an unreasonable risk of harm, those additional elements

narrowed the state requirements. Id. Therefore, the manufacturing and labeling claims based on violations of FDA regulations were not different from, or in addition to, federal requirements. Id. As such, MDA did not necessarily preempt Lohrs' claims. Id. at 497.

With these principles in mind, the Court will now evaluate whether Plaintiff has stated claims that are parallel to the federal requirements applicable to the MMT-522 System.

a. Strict products liability and negligence claims

Plaintiff's strict liability claim (Count I) asserts that the MMT-522 System that Plaintiff received had manufacturing, design, or marketing defects that caused his injury when it left Defendants' control. Am. Compl. ¶¶ 27-33. Plaintiff's failure-to-warn claim (Count II) asserts that Defendants knew or reasonably should have foreseen that its product presented an unreasonable risk of harm and failed to provide adequate warning and instruction on how to avoid that harm. Id. ¶¶ 34-39. Plaintiff's design-defect claim (Count III) asserts that the design of the MMT-522 System rendered it unreasonably dangerous and that a safer alternative design was feasible. Id. ¶¶ 40-43. Plaintiff's manufacturing-defect claim (Count IV) asserts that the MMT-522 System deviated from its

specifications or planned output, which made it unreasonably dangerous. Id. ¶¶ 44-47. And Plaintiff's negligence claim (Count VIII) asserts that Defendants' negligently designed, manufactured, and marketed the MMT-522 System. Id. ¶¶ 65-73. Plaintiff, therefore, generally asserts strict liability and negligence claims based on manufacturing, design, and warning defects.

Plaintiff's design-defect claims are preempted under MDA. Strict liability theories based on a device's alleged manufacturing and design defects and similar theories based in negligence are state requirements that are preempted by MDA because of their potential conflict with FDA labeling, design, and manufacturing requirements. See, e.g., Riegel, 552 U.S. at 330 (holding that claims based on strict liability and negligence preempted); Michael v. Shiley, Inc., 46 F.3d 1316, 1324-25 (3d Cir. 1995) (same), abrogated on other grounds by Medtronic, Inc. v. Lohr, 518 U.S. 468 (1996); Williams, 388 F. App'x at 171 (holding that claims based on strict liability for manufacturing defect preempted). Therefore, Plaintiff's designed-defect and manufacturing-defect claims are preempted by MDA because they are based on state requirements that are

different from, or in addition to, the relevant federal requirements.[12]

Nowhere in the Amended Complaint does Plaintiff allege that the claims asserted against Defendants are based on violations of any federal requirements. See Riegel, 552 U.S. at 330 (noting that plaintiffs failed to argue that certain claims were "premised on a violation of FDA regulations"). Despite this gap, and in the interest of completeness, the Court will construe Plaintiff's manufacturing-defect and failure-to-warn claims as premised on violations of FDA manufacturing and warning requirements for the MMT-522 System.[13]

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[12] Plaintiff asserts that Defense counsel conceded that he was in "agreement" that the negligence and breach-of-express-warranty claims should proceed in this case at the hearing on January 18, 2011. Pl.'s Answer to Defs.' Mot. for Summ. J. 9, ECF No. 38. Plaintiff has taken Defense counsel's statement out of context because that hearing was on Defendants' then-pending Motion to Dismiss.

[13] Plaintiff vaguely avers that the MMT-522 System "deviated, in its construction or quality, from its specifications or planned output." Am. Compl. ¶ 45. The Court will construe the "specifications" in the Amended Complaint to mean the specifications that the FDA promulgated for the MMT-522 System. And Plaintiff contends throughout his pleadings in response to the Motion for Summary Judgment that Plaintiff and his physician did not receive the warnings that were required by the FDA. The Court will construe Plaintiff's failure-to-warn claim as based on the alleged failure to provide the relevant FDA warnings.

b. Breach of implied warranty claims

Plaintiff's claim for breach of an implied warranty of fitness for a particular purpose (Count VI) asserts that Defendants breached an implied warranty because the MMT-522 System had a tendency to infuse the incorrect dosage of insulin. Am. Compl. ¶¶ 54-59. Plaintiff's claim for breach of an implied warranty of merchantability (Count VII) asserts the MMT-522 System was not merchantable for its intended use because of its tendency to infuse the incorrect dosage of insulin. Am. Compl. ¶¶ 60-64. Plaintiff's implied warranty claims are preempted by MDA.

Pennsylvania has adopted the Uniform Commercial Code formulations of the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. 13 Pa. Cons. Stat. §§ 2314, 2315; Borden, Inc. v. Advent Ink Co., 701 A.2d 255 (Pa. Super. Ct. 1997). The warranty of fitness exists "where the seller at the time of contracting has reason to know of such purpose and of the buyer's reliance upon the seller's skill or judgment to select or furnish goods that are suitable for such purpose." Borden, 701 A.2d at 258. The implied warranty of merchantability is "a warranty that the goods will pass without objection in the trade and are fit for the ordinary purposes for which such goods are used." Id. This warranty

"protect[s] buyers from loss where the goods purchased are below commercial standards." Id. (internal quotation marks removed).

Implied warranties in Pennsylvania are "centered around the accepted standards of design and manufacture of products in the state of Pennsylvania." Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004). The FDA, however, in its regulations and premarket approval relating to the MMT-522 System, has provided federal requirements relating to the design and manufacture of the MMT-522 System. Because Plaintiff's allegations relate to standards that are different from, or in addition to, the federal requirements, Plaintiff's implied warranty claims are preempted by MDA. See id.; see also Riegel, 552 U.S. at 330 (holding that implied-warranty claim preempted); Michael v. Shiley, Inc., 46 F. Supp. 3d 1316, 1324-25 (3d Cir. 1995) (same), abrogated on other grounds by Medtronic, Inc. v. Lohr, 518 U.S. 468 (1996); Williams, 388 F. App'x at 171 (same).

c. Breach of express warranty claim

Count V (breach of express warranty) is not preempted by MDA. Express warranties, as distinguished from implied warranties, do not independently arise by operation of state law. Importantly, the parties, not the state, "define[] the substantive obligations of the contract and hence any express

warranties." Michael, 46 F.3d at 1325 (holding that claim for breach of express warranty not preempted); Davenport, 302 F. Supp. 2d at 433 (same). Under Pennsylvania law, express warranties are created either by a seller's "affirmation of fact or promise" to a buyer, a "description of the goods," or a "sample or model," any of which is made a "basis of the bargain." 13 Pa. Cons. Stat. § 2313. Because "express warranties are specifically negotiated (rather than automatically implied by law), . . . the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." Goodman v. PPG Indus., Inc., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004). Plaintiff's claim for breach of express warranty does not involve a state "requirement" and is not preempted by MDA.[14] Therefore, Plaintiff's express warranty claim survives the Motion for Summary Judgment.[15]

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[14] The FDA's premarket approval letter confirms this conclusion because express warranties provided by Defendants in relation to the MMT-522 System were not evaluated by the FDA and are not, therefore, preempted by MDA. See Premarket Approval Letter (April 7, 2006), ECF No. 36-3 ("[Center for Devices and Radiological Health] does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.").

[15] The parties have not addressed whether, assuming Plaintiff's express warranty claim survives preemption, the claim can be disposed of at the summary judgment stage.

In summary, Plaintiff's claims in strict liability and negligence based on design defect and breach of implied warranties are preempted by MDA and will be dismissed. Plaintiff's express warranty claim is not preempted and survives the Motion for Summary Judgment. The Court will construe Plaintiff's manufacturing-defect and failure-to-warn claims as non-preempted parallel claims and will now consider whether those claims survive summary judgment.

C. Failure to Meet Summary Judgment Standard

Plaintiff's remaining claims based on manufacturing defect and failure to warn do not present triable issues of fact.

1. Manufacturing Defects

The Court construes Plaintiff's manufacturing-defect claims as premised on alleged failures to comply with FDA manufacturing requirements.[16] Defendants have proffered evidence that Plaintiff's MMT-522 System was free of defects before the

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Accordingly, the Court will not consider, at this point, whether Defendants are entitled to judgment as a matter of law on this claim.

[16] FDA "current good manufacturing practice" regulations "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished [medical] devices intended for human use." 21 C.F.R. § 820.1.

unit was shipped to Plaintiff. Medtronic's Senior Manager of External Pump Manufacturing, Donna Twisdom, who works in the manufacturing process of Medtronic's insulin pumps, submitted a declaration to the Court that explains that each device is manufactured according to FDA specifications provided in the premarket approval process. Twisdom Decl. 1-2, ECF No. 36-3. Furthermore, attached to the Twisdom Declaration, Defendants provided the quality control report for the device that Plaintiff received ("traveler"), which indicates that Plaintiff's device passed each quality assurance inspection and test, free of any manufacturing defects, and was packaged with the warnings and labeling approved by the FDA. Id. at 3 & Ex. A, B.

Plaintiff has failed to produce evidence that raises a genuine issue of material fact that his MMT-522 System departed from FDA manufacturing standards and therefore was defective. Naked denials of Defendants' proofs do not raise a genuine issue of material fact under Rule 56. See Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986); Lockhart v. Hoenstine, 411 F.2d 455, 459 (3d Cir. 1969).[17] Because Plaintiff has failed to set forth specific facts showing there is a genuine issue for trial,

[17] Under Pennsylvania state practice, a different result may ensue. See Borough of Nanty-Glo v. Am. Sur. Co. of N.Y., 163 A. 523, 524 (Pa. 1932) (holding that credibility of uncontradicted witnesses is matter for jury).

the Court will grant summary judgment for Defendants. See Williams v. Cyberonics, Inc., 654 F. Supp. 2d 301, 307 (E.D. Pa. 2009) (granting summary judgment on manufacturing defect claims when plaintiff failed to show genuine issue of material fact as to whether device departed from FDA-approved standards).

2. Failure to Warn

Defendants have proffered evidence that Plaintiff's physician prescribed the MMT-522 System to Plaintiff and that Defendants provided all FDA-required warnings. Plaintiff attempts to raise an issue of material fact by asserting that Defendants failed to include the requisite warnings that the MMT-552 System would deliver the incorrect dosage of insulin when exposed to strong electromagnetic fields. Plaintiff further asserts that he established a parallel state law claim because Defendants failed to provide Plaintiff's MMT-522 System only by a doctor's prescription and to warn physicians and users of the "danger involved with the recall of the MMT-522 pump." Pl.'s Answer to Defs.' Mot. for Summ. J. 10. Plaintiff, however, fails to raise a genuine issue of material fact. Therefore, the Court will grant summary judgment for Defendants with respect to the failure-to-warn claims.

a. Prescription for device

The FDA, in its premarket approval of the MMT-522 System and related federal regulations, restricts "[t]he sale, distribution, and use of [the modified MMT-515/715 device] to prescription use in accordance with 21 C.F.R. 801.109." Premarket Approval Letter 1 (April 7, 2006), ECF No. 36-3. Plaintiff's physician, Dr. Barilla, transmitted via facsimile a prescription that authorized Defendants to issue Plaintiff an MMT-522 System. The documentary evidence submitted by Defendants demonstrates that Dr. Barilla prescribed the MMT-522 System to Plaintiff. See Letter from Dr. Barilla (April 14, 2008) ("For the reasons stated above, I am prescribing a transmitter and sensors to be utilized with the Medtronic MiniMed 522/722 insulin infusion pump and continued pump and sensor supplies for Paul Bentzley."). Although notations on the prescription indicate that Dr. Barilla had not seen Plaintiff since 2006, an updated notation indicates "[patient] seen on 5/8/08." Id. Furthermore, the letter has a facsimile transmission time stamp of May 14, 2008, the date that Defendants' received the letter from Dr. Barilla's office. Id.

Dr. Barilla testified that the facsimile transmission date and notations were consistent with the prescribing documents that were transmitted to Medtronic on May 14, 2008, and that those documents would allow Medtronic to provide the

MMT-522 System to Plaintiff.[18] Dr. Barilla testified that he signed the prescription.[19] And Dr. Barilla further testified that he never communicated any concerns to Defendants that Plaintiff should not receive the MMT-522 System.[20]

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[18] Q. In your experience does that kind of notation mean that a FAX actually went out on that time?

A. Yeah, I think so.

Q. So would that be consistent with this having been FAX'd by your office to Medtronic on May 14th, 2008?

A. Yes.

Q. Would you expect Medtronic to provide a pump to Mr. Bentzley based on this prescription?

A. Yes.

Barilla Dep. 58: 17-25; see also id. 59:5-60:15 (confirming version of same document from Dr. Barilla's office).

[19] Q. Is that your signature on the bottom of this document?

A. Yes, it is.

Barilla Dep. 60:10-12.

[20] Q. Are you aware of any communication that you had with Medtronic, whether it be oral or written, in the period of April or May of 2008 to communicate any concerns or doubts that you had about whether Mr. Bentzley should receive a new pump?

. . .

A. No.

Barilla Dep. 60:16-61:2.

Plaintiff attempts to create a genuine issue of material fact by pointing to excerpts from Dr. Barilla's deposition that indicate that Dr. Barilla would not have prescribed the MMT-522 System to Plaintiff if he knew about the recall and Plaintiff's exposure to strong electromagnetic fields in his work environment. Pl.'s Surreply to Defs.' Mot. for Summ. J. 3-4. This aspect of Dr. Barilla's testimony is not relevant to the issue of whether Dr. Barilla prescribed the device to Plaintiff.[21]

Furthermore, Plaintiff attempts to create a genuine issue of material fact by pointing to Dr. Barilla's initial testimony that he did not prescribe the MMT-522 System to Plaintiff.[22] Later, however, Dr. Barilla testified that he had no

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[21] Indeed, this testimony would be more relevant in a malpractice action against Dr. Barilla for prescribing the MMT-522 System to Plaintiff without inquiring into whether he is routinely exposed to strong electromagnetic fields. Dr. Barilla's actions, however, are not at issue here. All that is relevant is whether Defendants, as required by FDA regulations and premarket approval of the MMT-522 System, distributed the MMT-522 System to Plaintiff pursuant to a physician's prescription.

[22] Q. Okay. By FAX'g this document back to Medtronic, were you telling Medtronic that you were not authorizing Paul Bentzley to get a new pump?

. . .

A. Yes.

Q. Okay. And why were you not authorizing the new pump?

independent recollection of whether he prescribed the MMT-522 System.[23] And when Defendants' counsel presented Dr. Barilla with his signed prescription, Dr. Barilla admitted that he prescribed the new device to Plaintiff.[24] The Court finds Dr. Barilla's

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A. I had very little data on him [Plaintiff]; I had no almost no data.

Barilla Dep. 31:16-32:3; see also id. 42:15-17 (Q: "But isn't it true, Doctor, that you never authorized Paul to have the 522 pump at all?; A: "That's correct.").

[23] Q. Do you have any independent recollection of whether or not you had prescribed a pump for Mr. Bentzley in 2008?

A. I do not.

Q. So your testimony today is based on what you are gathering from records that have been shown to you; is that correct?

A. That's correct.

Barilla Dep. 44:2-8.

[24] Q. And you signed Exhibit 21, is that right, the first page?

A. Yes, I did.

Q. All right. There are a couple of differences I'll just bring to your attention.

This is a——this is a copy, Exhibit 21, from Medtronic's records.

A. Uh-huh.

Q. It has a FAX transmittal date on there; do you see that?

A. I do.

Q. Can you read that FAX transmittal to me?

latter testimony admitting that he had indeed prescribed the device true.

It is true that a contradiction in testimony of a witness can raise a genuine issue of material fact. However, not every contradiction by a witness does so. Surely, if a witness testifies one way and is later impeached, or changes his testimony or seeks to explain it as a result of the impeachment, the contradiction raises an issue of fact as to which version of the facts, the original or the impeached version, is correct. On the other hand, if a witness testifies one way, and later, as a result of refreshing his recollection, such as by showing the witness a document, he changes the refreshed testimony, it is the latter testimony that stands.

A. May 14th, 2008.

Q. In your experience does that kind of notation mean that a FAX actually went out on that time?

A. Yea, I think so.

Q. So would that be consistent with this having been FAX'd by your office to Medtronic on May 14th, 2008?

A. Yes.

Q. Would you expect Medtronic to provide a pump to Mr. Bentzley based on this prescription?

A. Yes.

Barilla Dep. 58:4-25. Dr. Barilla provided similar testimony for the signed prescription marked Exhibit 6 to the Barilla Deposition. Id. 59:7-60:15.

For example, if a witness said he took a trip on Monday, but later in his testimony he is shown an airline ticket that indicates a Tuesday flight, and he adopts the refreshed testimony, then the change in testimony is not considered a contradiction.

Such is the case here where Dr. Barilla did not recollect from memory alone whether he prescribed the MMT-522 System to Plaintiff. Once his recollection was refreshed by showing him a copy of the signed prescription, which he confirmed he provided for Plaintiff to receive an MMT-522 System, the latter testimony stands on that issue without contradiction. Therefore, Plaintiff has not raised a genuine issue of material fact as to whether Defendants' distributed the MMT-522 System to Plaintiff without a physician's prescription.

b. FDA-required warnings

Plaintiff received the appropriate warnings as required by the FDA. Plaintiff wisely admits that he is "not arguing the adequacy of the warnings accompanying the prescription device." Pl.'s Answer to Defs.'s Mot. for Summ. J. 11. Indeed, doing so would present the Court with a claim that is different from, or in addition to, the relevant federal requirements, and would, therefore, be preempted. Instead, Plaintiff argues that the "very warnings required by the FDA did

not accompany the product at all." Id. However, Plaintiff has not clearly pointed the Court to the warnings to which he is referring. Two independent warning requirements seem to be at issue: (1) the warnings required by the FDA in the 2007 Class 2 Recall of the infusion pump for the MMT-522 and other models and (2) the warnings required by the FDA to accompany the MMT-522 system.

Whether Plaintiff received the 2007 warnings for the Class 2 recall in 2007 is irrelevant. The 2007 recall did not physically recall any of Defendants' medical devices. Instead, after learning that the pumps associated with certain systems would over deliver insulin after exposure to strong electromagnetic fields, Defendants mailed users of the relevant devices warning letters that reiterated existing warnings that were already included with the devices.[25] Plaintiff, during the 2007 recall, did not yet own the MMT-522 System, which, he

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[25] The FDA's report of the Class 2 Recall provides,

> Firm mailed Medical Device Safety letters on April 24, 2007, to healthcare professionals, existing pump users and MRI facilities reiterating the existing warning in the pump User Guide to avoid exposing the pump to MRI (or similar high strength electromagnetic fields) and strengthening previous warning by specifically mentioning the potential for over-delivery and severe hypoglycemia. Firm is also including an insert with this information with any Paradigm infusion pumps shipped to new customers.

Pl.'s Answer to Defs.' Mot. for Summ. J. Ex. E, ECF No. 38-1.

alleges, caused his injuries. Therefore, whether Plaintiff received the additional warnings for the MMT-512 pump in 2007 is immaterial.[26] But the recall also required that Defendants include the additional warnings for any new customer of the relevant pumps. Because Plaintiff became a "new customer" of the MMT-522 System in 2008, he should have received the additional recall warnings with his new MMT-522 System.

Defendants have proffered evidence showing there is no genuine issue of material fact that Plaintiff received the appropriate warnings and that they are entitled to judgment as a matter of law. Defendants have pointed to evidence that the MMT-522 System shipped to Plaintiff included all the warnings required by the FDA. And Defendants proffered evidence that Plaintiff's pump was packaged with a User Guide that contained the appropriate warnings required by the FDA. See Twisdom Decl. ¶ 10 (swearing that Plaintiff's MMT-522 System was "packaged with the warnings and labeling approved by the FDA"). The User Guide warns against exposing the device to strong electromagnetic fields.[27] User Guide 6. Furthermore, the "Order

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[26] Plaintiff seems to acknowledge this conclusion in later pleadings despite his prior arguments regarding the 2007 recall. See Pl.'s Surreply to Defs.' Mot. for Summ. J. 4.

[27] Specifically, the User Guide warns,

> X-rays, MRIs and CT scans

Pick List," which identifies every item that was packaged with an individual's order, for Plaintiff's pump demonstrates that an "MRI WARNING SHEET, INSULIN PUMP," the additional warning required by the 2007 recall, was packaged with Plaintiff's order.[28] See Macal Decl. ¶¶ 4, 7 & Ex. C, ECF No. 36-3.

Plaintiff, on the other hand, has not raised a genuine issue of material fact that he did not receive the additional 2007 recall warnings and the warnings that would have normally

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> If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, **take off your pump, meter and remote control** and remove them from the area.
>
> The Paradigm pump is designed to withstand common electromagnetic interference, including airport security systems. Be sure to carry the Airport Card provided when you are traveling.

User Guide 6 (emphasis in original).

[28] The MRI Warning Sheet provides,

> WARNING
>
> **DO NOT** expose your insulin pump to MRI equipment or other devices that generate very strong magnetic fields. The magnetic fields in the immediate vicinity of these devices can damage the part of the pump's motor that regulates insulin delivery, possibly resulting in over-delivery and sever hypoglycemia. **YOUR PUMP MUST BE REMOVED AND KEPT OUTSIDE THE ROOM DURING MAGNETIC IMAGING (MRI) PROCEDURES.**
>
> If your pump is inadvertently exposed to a strong magnetic field, discontinue use and contact your local Medtronic MiniMed help line for further assistance.

Macal Decl. Ex. A (emphasis in original). The warning also included a "No MRI" icon. Id.

accompanied a new MMT-522 System. Plaintiff has not pointed to evidence of record that he did not receive these warnings. Instead, Plaintiff contests that the Order Pick List demonstrates that the relevant warnings were never inserted because the Order Pick List was not "checked, initialed, signed, or dated," nor signed in a field marked "Signature: **REQUIRED**." Pl.'s Answer to Defs.' Mot. for Summ. J. 13-14 (emphasis in original). Plaintiff compares the Order Pick List to the "traveler" attached to the Twisdom Declaration that showed the quality control tests conducted on Plaintiff's MMT-522 System. The traveler is heavily marked with initialing and dating. The Order Pick List is not.

But this comparison does not raise a genuine issue of material fact. First, Plaintiff's comparison of the traveler and the Order Pick List is unavailing because the two documents serve different purposes. The traveler is used to document each quality control test conducted on the relevant device, when the device was tested, and by whom. The Order Pick List, while important, serves a different purpose. It documents what materials were packaged with each order. Furthermore, as the Medtronic Director of Global Supply Chain Services provided, a lack of notation on the Order Pick List indicates that all items identified were packaged. Macal Supp. Decl. ¶¶ 3-5, ECF No. 40-4. And the "Signature: **REQUIRED**" field directs the shipping

carrier——here, UPS——to secure a signature upon delivery of the package——not that a Medtronic employee must sign the Order Pick List to certify its accuracy, as Plaintiff contends. Id. ¶ 4.

Bare allegations that he did not receive these warnings with his MMT-522 System are not sufficient to raise a genuine issue of material fact, especially in light of the overwhelming evidence Defendants proffered that shows that the FDA-required warnings were packaged with Plaintiff's device.[29] See Celotex Corp., 477 U.S. at 323-24. Therefore, the Court will grant Defendants' Motion for Summary Judgment as to Plaintiff's failure-to-warn claims.

III. CONCLUSION

For the reasons stated above, the Court will **grant** Defendants' Motion for Summary Judgment in part and **dismiss** Counts I, II, III, IV, VI, VII, VIII, and IX. The Court will **deny** Defendants' Motion as to Count V (breach of express warranty). An appropriate order will follow.

[29] Because the Court dispenses of the case on the basis that Defendants sent the appropriate warnings to Plaintiff with his MMT-522 System, the Court will not reach Defendants' alternative argument that Defendants were only required to warn the "learned intermediary," that is, Plaintiff's physician. See Defs.' Reply Mem. in Support of Mot. for Summ. J. 11-13.